

product under the Virus-Serum-Toxin Act was submitted before November 16, 1988, by—

(A) Adding 5 years to the original expiration date of the patent or earlier date set by terminal disclaimer; and

(B) Comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(i)(A) of this section with each other and selecting the earlier date; or

(ii) If a request for the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act was submitted before November 16, 1988, and the commercial marketing or use of the product was not approved before November 16, 1988, by—

(A) Adding 3 years to the original expiration date of the patent or earlier date set by terminal disclaimer; and

(B) Comparing the dates obtained pursuant to paragraphs (d)(4) and (d)(6)(ii)(A) of this section with each other and selecting the earlier date.

[52 FR 9394, Mar. 24, 1987, as amended at 54 FR 30382, July 20, 1989]

#### **§ 1.780 Certificate or order of extension of patent term.**

If a determination is made pursuant to § 1.750 that a patent is eligible for extension and that the term of the patent is to be extended, a certificate of extension, under seal, or an order granting interim extension under 35 U.S.C. 156(d)(5), will be issued to the applicant for the extension of the patent term. Such certificate or order will be recorded in the official file of the patent and will be considered as part of the original patent. Notification of the issuance of the certificate or order of extension will be published in the *Official Gazette of the United States Patent and Trademark Office*. Notification of the issuance of the order granting an interim extension under 35 U.S.C. 156(d)(5), including the identity of the product currently under regulatory review, will be published in the *Official Gazette of the United States Patent and Trademark Office* and in the FEDERAL REGISTER. No certificate of, or order granting, an extension will be issued if the term of the patent cannot be extended, even though the patent is otherwise determined to be eligible for extension. In such situations, the final determination made pursuant to § 1.750

will indicate that no certificate or order will issue.

[65 FR 54680, Sept. 8, 2000]

#### **§ 1.785 Multiple applications for extension of term of the same patent or of different patents for the same regulatory review period for a product.**

(a) Only one patent may be extended for a regulatory review period for any product (§ 1.720(h)). If more than one application for extension of the same patent is filed, the certificate of extension of patent term, if appropriate, will be issued based upon the first filed application for extension.

(b) If more than one application for extension is filed by a single applicant which seeks the extension of the term of two or more patents based upon the same regulatory review period, and the patents are otherwise eligible for extension pursuant to the requirements of this subpart, in the absence of an election by the applicant, the certificate of extension of patent term, if appropriate, will be issued upon the application for extension of the patent term having the earliest date of issuance of those patents for which extension is sought.

(c) If an application for extension is filed which seeks the extension of the term of a patent based upon the same regulatory review period as that relied upon in one or more applications for extension pursuant to the requirements of this subpart, the certificate of extension of patent term will be issued on the application only if the patent owner or its agent is the holder of the regulatory approval granted with respect to the regulatory review period.

(d) An application for extension shall be considered complete and formal regardless of whether it contains the identification of the holder of the regulatory approval granted with respect to the regulatory review period. When an application contains such information, or is amended to contain such information, it will be considered in determining whether an application is eligible for an extension under this section. A request may be made of any applicant to supply such information within a non-extendable period of not less

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than one month whenever multiple applications for extension of more than one patent are received and rely upon the same regulatory review period. Failure to provide such information within the period for reply set shall be regarded as conclusively establishing that the applicant is not the holder of the regulatory approval.

(e) Determinations made under this section shall be included in the notice of final determination of eligibility for extension of the patent term pursuant to § 1.750 and shall be regarded as part of that determination.

[60 FR 25618, May 12, 1995, as amended at 62 FR 53201, Oct. 10, 1997]

## § 1.790 Interim extension of patent term under 35 U.S.C. 156(d)(5).

(a) An owner of record of a patent or its agent who reasonably expects that the applicable regulatory review period described in paragraph (1)(B)(ii), (2)(B)(ii), (3)(B)(ii), (4)(B)(ii), or (5)(B)(ii) of subsection (g) that began for a product that is the subject of such patent may extend beyond the expiration of the patent term in effect may submit one or more applications for interim extensions for periods of up to one year each. The initial application for interim extension must be filed during the period beginning 6 months and ending 15 days before the patent term is due to expire. Each subsequent application for interim extension must be filed during the period beginning 60 days before and ending 30 days before the expiration of the preceding interim extension. In no event will the interim extensions granted under this section be longer than the maximum period of extension to which the applicant would be entitled under 35 U.S.C. 156(c).

(b) A complete application for interim extension under this section shall include all of the information required for a formal application under § 1.740 and a complete application under § 1.741. Sections (a)(1), (a)(2), (a)(4), and (a)(6)–(a)(17) of § 1.740 and § 1.741 shall be read in the context of a product currently undergoing regulatory review. Sections (a)(3) and (a)(5) of § 1.740 are not applicable to an application for interim extension under this section.

(c) The content of each subsequent interim extension application may be

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limited to a request for a subsequent interim extension along with a statement that the regulatory review period has not been completed along with any materials or information required under §§ 1.740 and 1.741 that are not present in the preceding interim extension application.

[60 FR 25619, May 12, 1995]

## § 1.791 Termination of interim extension granted prior to regulatory approval of a product for commercial marketing or use.

Any interim extension granted under 35 U.S.C. 156(d)(5) terminates at the end of the 60-day period beginning on the date on which the product involved receives permission for commercial marketing or use. If within that 60-day period the patent owner or its agent files an application for extension under §§ 1.740 and 1.741 including any additional information required under 35 U.S.C. 156(d)(1) not contained in the application for interim extension, the patent shall be further extended in accordance with the provisions of 35 U.S.C. 156.

[60 FR 25619, May 12, 1995]

## Subpart G—Biotechnology Invention Disclosures

### DEPOSIT OF BIOLOGICAL MATERIAL

SOURCE: 54 FR 34880, Aug. 22, 1989, unless otherwise noted.

## § 1.801 Biological material.

For the purposes of these regulations pertaining to the deposit of biological material for purposes of patents for inventions under 35 U.S.C. 101, the term biological material shall include material that is capable of self-replication either directly or indirectly. Representative examples include bacteria, fungi including yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens and seeds. Viruses, vectors, cell organelles and other non-living material existing in and reproducible from a living cell may be deposited by deposit of the host cell capable of reproducing the non-living material.